

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 10/791,447
Applicant: Janzen Lo et al.
Filed: March 2, 2004
Title: SURGICAL INSTRUMENT FOR IMPLANTS
T.C./A.U.: 3733
Examiner: Mary C. Hoffman
Confirmation No.: 3444
Notice of Appeal Filed: January 6, 2010
Docket No.: BBM-147US

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated October 6, 2009, of claims 1, 3-5, 20 and 21.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

A fee for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2) was paid at the time of filing of the September 15, 2008 Appeal Brief. The difference between the current fee and the fee paid at that time is provided herewith.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Aesculap II, Inc. by virtue of an assignment recorded on May 11, 2007, at Reel/Frame 019286/0034.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal.

III. STATUS OF CLAIMS

Claims 1 and 3-21 are pending, with claims 6-19 withdrawn, and claim 2 canceled. Claims 1, 3-5, 20 and 21 stand rejected. Claims 1 and 3-5, 20 and 21 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

As set forth in the pending independent apparatus claim 1, the presently claimed invention relates to an implant insertion device 60 as shown generally in Figs. 14-20. As explained in the specification at page 14, lines 27-29, the purpose of the implant insertion device 60 is to guide a bone implant 10, 10', 10", 10"" to an implantation site in a patient's body and deposit the bone implant 10, 10', 10", 10"" in the implantation site.

Referring to the specification beginning at page 14, line 18, the implant insertion device 60 includes a handle 62, an insertion rod 64 that is attached to the handle 62, and an implant gripper 66 attached to the insertion rod 64. The implant gripper 66 includes a gripping surface 68. Referring to Fig. 15, a movable pin 70 and a fixed pin 72 are located on and extend from the gripping surface 68. Also included is a pin actuator 74 for moving the movable pin 70 between an extended position and a retracted position relative to the gripping surface 68.

As explained at beginning at page 15, line 11, the gripping surface 68 may be in the form of a v-shape to accommodate and effectively abut the flat sidewall portions 20, 20', 20", 20"" of the bone implant 10, 10', 10", 10"", as shown in Figs. 15 and 16. Preferably, the movable pin 70 and the fixed pin 72 make an angle phi 76 of about 30 degrees. This angle phi 76 is in accordance with the angle theta 30 of about 30 degrees of the first embodiment of the implant 10 so that the movable pin 70 and the fixed pin 72 fit flushly inside the insertion pin holes 22 and 26.

As further explained beginning at page 16, line 1, the pin driving shaft 82 is sized to accommodate a pin driver 84 that can be attached to the movable pin 70 in order to drive the movable pin 70 into a insertion pin hole 26, 26', 26", 26"". Activating the pin actuator 74 causes the pin driver 84 to drive the movable pin 70 into the insertion pin hole 26, 26', 26", 26"". As shown in Figures 19 and 20, the movable pin 70 is movable between a retracted position (Figure 19) and an extended position (Figure 20).

As set forth in the pending independent apparatus claim 20, the presently claimed invention relates to an implant insertion device 60 as shown

generally in Figs. 14-20. As explained in the specification at page 14, lines 27-29, the purpose of the implant insertion device 60 is to guide a bone implant 10, 10', 10", 10''' to an implantation site in a patient's body and deposit the bone implant 10, 10', 10", 10''' in the implantation site.

Referring to the specification beginning at page 14, line 18, the implant insertion device 60 includes a handle 62, an insertion rod 64 that is attached to the handle 62, and an implant gripper 66 attached to the insertion rod 64. The implant gripper 66 includes a gripping surface 68. Referring to Fig. 15, the longitudinal axis of the insertion rod 64 intersects the gripping surface 68. Also with reference to Fig. 15, a movable pin 70 and a fixed pin 72 are located on and extend from the gripping surface 68. Preferably, the movable pin 70 and the fixed pin 72 make an angle ϕ 76 of about 30 degrees. This angle ϕ 76 is in accordance with the angle θ 30 of about 30 degrees of the first embodiment of the implant 10 so that the movable pin 70 and the fixed pin 72 fit flushly inside the insertion pin holes 22 and 26. Also included is a pin actuator 74 for moving the movable pin 70 between an extended position and a retracted position relative to the gripping surface 68 (see Figs. 19 and 20).

As set forth in the pending independent apparatus claim 21, the presently claimed invention relates to an implant insertion device 60 as shown generally in Figs. 14-20. As explained in the specification at page 14, lines 27-29, the purpose of the implant insertion device 60 is to guide a bone implant 10, 10', 10", 10''' to an implantation site in a patient's body and deposit the bone implant 10, 10', 10", 10''' in the implantation site.

Referring to the specification beginning at page 14, line 18, the implant insertion device 60 includes a handle 62, an insertion rod 64 that is attached to the handle 62, and an implant gripper 66 attached to the insertion rod 64. The implant gripper 66 includes a gripping surface 68. Referring to Fig. 15, the longitudinal axis of the insertion rod 64 intersects the gripping surface 68. Also with reference to Fig. 15, a movable pin 70 and a fixed pin 72 are located on and extend from the gripping surface 68. Also included is a pin actuator 74 for moving the movable pin 70 between an extended position and a retracted position relative to the gripping surface 68 (see Figs. 19 and 20).

As explained at beginning at page 15, line 11, the gripping surface 68 may be in the form of a v-shape to accommodate and effectively abut the flat sidewall portions 20, 20', 20", 20''' of the bone implant 10, 10', 10", 10''' as shown in Figs. 15 and 16. Preferably, the movable pin 70 and the fixed pin 72 make an angle ϕ 76 of about 30 degrees. This angle ϕ 76 is in accordance with the angle θ 30 of about 30 degrees of the first embodiment of the implant 10 so that the movable pin 70 and the fixed pin 72 fit flushly inside the insertion pin holes 22 and 26.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 3-5, 20 and 21 are unpatentable under 35 U.S.C. § 102(e) based on Zucherman et al.

VII. ARGUMENT

A. § 102(e) Rejection

Claims 1, 3-5 and 20-21 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Published Application No. 2008/0027552 (Zucherman et al.). Appellants traverse these rejections.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

It is respectfully submitted, however, that none of the cited prior art references teach the subject matter recited in independent claims 1, 20 and 21 or their respective dependent claims. Significantly, none of the cited art, either alone or in combination, teach an implant insertion device including first and second pins that are offset on the gripping surface and extend in a non-parallel manner.

Independent claim 1 recites "[a]n implant insertion device comprising: an insertion rod having a longitudinal axis; and an implant gripper attached to said insertion rod, said implant gripper including: a v-shaped gripping surface intersecting the longitudinal axis of the insertion rod; a first pin extending from and fixed relative to said v-shaped gripping surface; and a second pin extending through and movable relative to said v-shaped gripping surface between a first position wherein the second pin extends from the v-shaped gripping surface a distance x and a second position wherein the second pin extends a distance less than x from the v-shaped gripping surface, wherein said first pin and said second pin are offset on said v-shaped gripping surface and extend in a non-parallel manner."

Similarly, independent claim 20 recites "[a]n implant insertion device comprising: an insertion rod having a longitudinal axis; and an implant gripper extending from said insertion rod, said implant gripper including: an implant gripping surface intersecting the longitudinal axis of the insertion rod; a first pin extending from and fixed relative to said implant gripping surface; and a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin."

Independent claim 21 recites "[a]n implant insertion device comprising: a handle having a gripping surface; an insertion rod extending from said handle, said insertion rod defining a longitudinal axis; an implant gripper extending from said insertion rod, said implant gripper including: an implant gripping surface intersecting the longitudinal axis of the insertion rod; a first pin extending from and fixed relative to said implant gripping surface; and a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin; and an actuator positioned proximal to said handle for moving the second pin relative to said v-shaped gripping surface."

Each of the independent claims recites a gripping surface intersecting the longitudinal axis of the insertion rod. A first pin extends from this gripping surface. Additionally, a second pin extends through and is moveable relative to this gripping surface. This configuration allows the implant to be held securely while allowing the tool to be easily removed from the implant with an axial motion, thereby requiring minimal space.

Zucherman et al. does not teach or suggest the claimed invention. The Office Action cites to the implant gripper (5030) shown in Figs. 184, 185 and 194. During a telephone interview, the Examiner acknowledged that she had not identified a specific gripping surface, but instead was looking at the shape of the insertion tip 5030. The October 6, 2009 Final Office Action includes a marked up version of a portion of Fig. 194, which merely shows a heavy "U-shaped" line marked as the "gripping surface" however this marked up figure provides no further

clarification of the gripping surface relied upon in the Final Office for the rejection of the claims.

With respect to Figs. 186a-186c and 194, pins 5560, which are indicated in the Office Action as equivalent to the recited first pin, extend from surface 5565. As shown in Fig. 186a, surface 5565 does not intersect the longitudinal axis of the insertion rod. To the contrary, surface 5565 extends parallel to the longitudinal axis of the insertion rod and thereby, pins 5560 extend perpendicular to the axis. With this configuration, the tool 5500 must be moved in a direction perpendicular to the longitudinal axis to disengage the tool 5500 from an implant, thereby requiring additional space around the implant.

Furthermore, driver 5555, which is indicated in the Office Action as equivalent to the recited second pin, does not extend through and move relative to the surface 5565. Instead, as shown in Figs. 186a-186c, the driver 5555 extends parallel to the surface 5565 and not through the surface 5565 and moves within the opening 5567 which is clear of the surface 5565.

Zucherman et al. alone or in any reasonable combination fails to teach or suggest each limitation of the claimed invention.

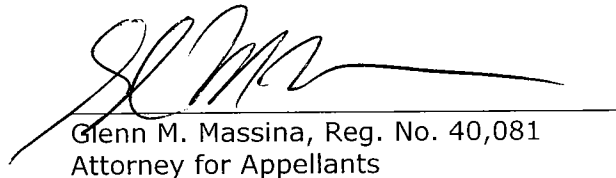
It is respectfully submitted that independent claims 1, 20 and 21 are in condition for allowance. Claims 3-5 all ultimately depend from claim 1 and are therefore allowable for, inter alia, the reasons set forth above. Additionally, withdrawn claims 6-19 all ultimately depend from independent claim 1 and should be reinstated and allowed as dependent upon an allowable generic claim.

VIII. CONCLUSION

In view of the arguments set forth above, all pending claims are patentable over the cited references. The rejection of all of the pending claims of record should therefore be reversed with instructions to issue a Notice of Allowability. Moreover, Appellants request reconsideration and allowance of claims 6-19, which are withdrawn to a nonelected species, upon the allowance of the generic claim. Such actions are respectfully requested.

Respectfully Submitted,

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Enclosures: Claims Appendix
Evidence Appendix
Related Proceedings Appendix

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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

CLAIMS APPENDIX

1. An implant insertion device comprising:
an insertion rod having a longitudinal axis; and
an implant gripper attached to said insertion rod, said implant gripper
including:
a v-shaped gripping surface intersecting the longitudinal axis of the insertion
rod;
a first pin extending from and fixed relative to said v-shaped gripping surface;
and
a second pin extending through and movable relative to said v-shaped
gripping surface between a first position wherein the second pin extends from the v-
shaped gripping surface a distance x and a second position wherein the second pin
extends a distance less than x from the v-shaped gripping surface,
wherein said first pin and said second pin are offset on said v-shaped gripping
surface and extend in a non-parallel manner.
2. (Canceled)
3. The insertion device of claim 1, wherein said first pin and said second pin
are offset on said gripping surface by an angle of approximately 30 degrees.
4. The insertion device of claim 1, wherein said first pin and said second pin
are smooth.
5. The insertion device of claim 1, wherein said implant gripper is removable
from said insertion rod.

6. A method of engaging an implant with an implant insertion device according to claim 1, comprising the steps of:

(a) retracting the second pin relative to the gripping surface of the implant insertion device;

(b) positioning the implant adjacent to the gripping surface such that the first pin extending from the gripping surface extends into an insertion pin hole of the implant; and

(c) extending the second pin relative to the gripping surface such that the second pin extends into a second insertion pin hole of the implant, thereby effectively reversibly locking the implant onto said device.

7. The method of claim 6 further comprising the step of

(a) retracting the second pin of the implant gripper from the insertion pin hole of the implant; and

(b) moving the gripping surface away from the implant such that the first pin is removed from the second insertion pin hole of the implant and the implant insertion device is disengaged from the implant device.

8. A method of insertion of an implant with an implant insertion device according to claim 1, comprising the steps of:

(a) attaching the implant to the implant insertion device by retracting the second pin relative to the gripping surface of the implant insertion device; positioning the implant adjacent to the gripping surface such that the first pin extending from the gripping surface extends into an insertion pin hole of the implant, and extending the second pin relative to the gripping surface such that the second pin extends into a second insertion pin hole of the implant;

(b) inserting said implant in a spinal column; and

(c) detaching said implant from said implant insertion device by retracting said second pin from said second insertion pin hole of said implant, and detaching said first pin of said implant gripper from said insertion pin hole of the implant.

9. An implant insertion assembly comprising:

an implant insertion device according to claim 1; and

an implant comprising an outer sidewall which defines one or more insertion pin holes configured to receive the first and second pins.

10. The assembly according to claim 9, wherein said insertion pin holes include a counter bore cut.

11. The assembly according to claim 9, wherein the implant outer sidewall includes at least two flat sidewall portions and first and second insertion pin holes are defined along the respective flat sidewall portions.

12. The assembly according to claim 9, wherein said implant includes a superior end face and an inferior end face and one or both of said superior end face and said inferior end face include a plurality of radial cuts.

13. The assembly according to claim 12, wherein said plurality of radial cuts are tiered.

14. The assembly according to claim 9, wherein said implant includes a superior end face and an inferior end face and one or both of said superior end face and said inferior end face include a plurality of concentric cuts.

15. The assembly according to claim 14, wherein said plurality of concentric cuts are tiered.

16. The assembly according to claim 9, wherein said implant includes a superior end face and an inferior end face and one or both of said superior end face and said inferior end face include a plurality of concentric cuts and a plurality of radial cuts.

17. The assembly according to claim 9, wherein said implant defines a hollow core.

18. The assembly according to claim 9, wherein said implant is a biocompatible material.

19. The assembly according to claim 9, wherein said implant insertion device is a biocompatible material.

20. An implant insertion device comprising:
an insertion rod having a longitudinal axis; and
an implant gripper extending from said insertion rod, said implant gripper including:
an implant gripping surface intersecting the longitudinal axis of the insertion rod;
a first pin extending from and fixed relative to said implant gripping surface; and
a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin.

21. An implant insertion device comprising:
a handle having a gripping surface;
an insertion rod extending from said handle, said insertion rod defining a longitudinal axis;
an implant gripper extending from said insertion rod, said implant gripper including:
an implant gripping surface intersecting the longitudinal axis of the insertion rod;

a first pin extending from and fixed relative to said implant gripping surface; and

a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin; and

an actuator positioned proximal to said handle for moving the second pin relative to said v-shaped gripping surface.

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EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None